AUG 1 0 2001

NORTECH

K011928

SUMMARY OF SAFETY AND EFFECTIVENESS

Common/Usual Name: Arthroscope and Accessories

Proprietary Name: Hydrotower® Arthroscopic Administration Tubing Set

Classification: Class II

Materials:

Materials used to manufacture the Nortech® Hydrotower® Arthroscopic Administration Tubing Set are non-toxic and have been previously used to manufacture other devices.

Description:

The Hydrotower® Arthroscopic Administration Tubing Set is designed to be used with the Nortech® Hydrotower® System. The device is comprised of pvc tubing, check valve, a pressure relief valve, and numerous polymer fittings.

Substantial Equivalence:

Northgate's Hydrotower® Arthroscopic Administration Tubing Set is a tubing set that is substantially equivalent in design materials, and intended use to numerous currently marketed devices. Northgate manufactures similar devices as indicated in Exhibits # 1/ # 2.

Intended Use:

The Nortech® Hydrotower® Arthroscopic Administration Tubing Set shall be used to move fluid from the tower bag to the patient.

Northgate Technologies Incorporated 600 Church Road, Elgin, IL 60123 1-800-348-0424 IL: 847-608-8900 FAX: 847-608-9405

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2001

Mr. Casey Kurek
Regulatory Manager
Northgate Technologies, Inc.
600 Church Road
Elgin, Illinois 60123

Re: K011928
Trade/Device Name: The Hydrotower® Arthroscopic Administration Tubing Set
Regulation Number: 880.5440, 876.1500
Regulatory Class: II
Product Code: FPA, GCJ
Dated: June 18, 2001
Received: June 20, 2001

Dear Mr. Kurek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NORTECH

CONFIDENTIAL

510 (k) Number (If known): K011928

Device Name: THE HYDROTOWER® ARTHROSCOPIC ADMINISTRATION TUBING SET

Indications For Use:

THE HYDROTOWER® ARTHROSCOPIC ADMINISTRATION TUBING SET IS USED TO MOVE FLUID FROM THE TOWER BAG TO THE PATIENT.

Casey Kurek

C. Kurek, Regulatory Manager

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Milhous (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011928

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